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10/622,774	07/21/2003	David Hildebrand	50229-377	4235

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600 13th Street,, N.W.
Washington, DC 20005-3096

EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

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09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,774

Applicant(s)

HILDEBRAND ET AL.

Examiner

Vinod Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, and 25-31 is/are rejected.
- 7) ☒ Claim(s) 23, 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/14/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on June 22, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Newly added claims 20-36 are pending. Claims 20-31 directed to elected Group I are examined in the instant Office action. Objection to the specification is withdrawn in light of amendment to the abstract filed in the paper of June 22, 2007. Objection to Drawings is withdrawn in light of amendment to the Drawings filed in the paper of June 22, 2007. All previous rejections not set forth below have been withdrawn in view of claim amendments. This action is made FINAL.

Election/restriction

2. Newly added claims 32-36 directed to non-elected invention of Group II are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 18, 2006. The restriction was made final in the Office action mailed on November 28, 2006.

Claims 32-36 which was nonelected with traverse in the reply filed on September 18, 2006. A complete reply to the final rejection must include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449 filed on 05/14/2004 is attached to the instant Office action. Document No. EP 0267159A2 was not considered because English translation was not provided.

In the paper of June 22, 2007, Applicants state that an English translation of the abstract of the document is provided. However, it is noted that no such English translation of the abstract of Document No. EP 0267159A2 is provided.

Claim Objections

4. Claims 23, 24, and 30 are objected due to following informalities:

Claims 23 and 24 are objected for depending on rejected claim 20.

In claim 30, change the recitation "claim 30" to "claim 29".

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

5. Newly added claims 20-22, and 25-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a delta 12-fatty acid epoxygenase enzyme which has the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for a nucleic acid molecule encoding a protein which has less than 100% sequence identity to SEQ ID

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NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record as stated in the Office action of November 18, 2006. Applicants traverse the rejection in the paper filed on June 22, 2007.

Applicants argue that example 6 on page 17 and 18 of the specification teach the isolation of an analogue, homolog or derivative of *Stokesia laevis* delta 12-epoxygenase gene using probes that are specific for the gene (response, page 13, lines 14-17).

Applicants file 1.132 declaration to support their arguments.

Applicant's arguments were fully considered but were not found to be persuasive. It is important to note that claims 20, 29, and 31 are directed to a nucleic acid sequence encoding a protein which has 90% sequence identity to instant SEQ ID NO: 2. Further, claim 21 is directed to a nucleic acid sequence encoding a protein which has 95% sequence identity to SEQ ID NO: 2, and claim 22 is directed to a nucleic acid sequence encoding a protein which has 98% sequence identity to SEQ ID NO: 2.

It is maintained that these claims encompass amino acid sequences having less than 100% sequence identity to SEQ ID NO: 2 and having epoxygenase activity. An amino acid sequence with 90% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 37 amino acid substitutions in the amino acid sequence of SEQ ID NO: 2. An amino acid sequence with 95% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 18 amino acid substitutions in the amino acid sequence of SEQ ID NO: 2. Likewise, an amino acid sequence with 98% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 9 amino acid

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substitutions in the amino acid sequence of SEQ ID NO: 2. Thus claims encompass amino acid sequences having unspecified amino acid changes in the amino acid sequence of SEQ ID NO: 2.

It is maintained that neither the state of related art nor the specification provide guidance on which region(s) protein SEQ ID NO: 2 can be altered without abrogating delta 12-fatty acid epoxygenase activity. It is further maintained that neither the specification nor the related art provide guidance on the conserved (including signature pattern) functional domains that are essential for the 12-fatty acid epoxygenase activity. It is further maintained that the specification and the related art fails to provide guidance on the amino acid residues within SEQ ID NO: 2 that are essential for maintaining a stable 3D structure of SEQ ID NO: 2. In this regard, it is important to note the teachings of Guo et al. who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, a sequence identity of 90-98% to SEQ ID NO: 2 would result in higher proportion of variants lacking 12-fatty acid epoxygenase activity.

Applicants are reminded that the issue is *not* whether experimentation was required at the time claimed invention was made to determine how to isolate nucleotide sequences which are derivative of SEQ ID NO: 2. Rather, the issue is whether the experimentation required was undue at the time the claimed invention was made, based upon the various factors previously discussed, and further outlined above. It is noted that Applicant's 1.132 declaration filed in the paper of June 22, 2007 fails to address the enablement issue pertaining to variants of SEQ ID NO: 2.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed previously and further outlined above, it is maintained that undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to practice the invention commensurate in scope with these claims.

6. Newly added claims 20-22, and 25-31 are rejected under 35 U.S.C. 112, first paragraph are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record as stated in the Office action of November 18, 2006. Applicants traverse the rejection in the paper filed on June 22, 2007.

Applicants argue that the specification discloses in Example 6, pages 17 and 18 of the specification, the isolation of an analogue, homolog or derivative of *Stokesia laevis* 12-epoxygenase gene, using high stringency conditions. Applicants further argue that a person having reasonable skill in the art would understand that the use of high stringency conditions described in Example 6 clearly discloses nucleic acid molecule encoding a protein having at least 90% identity to SEQ ID NO: 2. Applicants further argue that the presently claimed invention correlates to the function of epoxygenase activity when expressed in a plant (response, page 15, lines 14-21; page 16, lines 1-6).

Applicant's arguments were fully considered but were not found persuasive. It is maintained that these claims encompass amino acid sequences having less than 100%

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sequence identity to SEQ ID NO: 2 and having epoxygenase activity. An amino acid sequence with 90% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 37 amino acid substitutions in the amino acid sequence of SEQ ID NO: 2. An amino acid sequence with 95% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 18 amino acid substitutions in the amino acid sequence of SEQ ID NO: 2. Likewise, an amino acid sequence with 98% sequence identity to the 378 amino acid long SEQ ID NO: 2 would comprise 9 amino acid substitutions in the amino acid sequence of SEQ ID NO: 2. Thus claims encompass amino acid sequences (structures) having unspecified amino acid changes in the amino acid sequence of SEQ ID NO: 2.

The specification does not describe the structures of Applicant's broadly genus, and further fail to correlate said structures to the function of 12-fatty acid epoxygenase activity. Thus, there is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of a nucleic acid sequence encoding SEQ ID NO: 2.

The only species described in the specification is SEQ ID NO: 1 which encodes SEQ ID NO: 2. Thus one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing.

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See *in re Curtis* (69 USPQ2d 1274 (Fed. Cir.2004)), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other than the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would "instantly recall" additional species of the genus already "stored" in the minds, but if other members of the genus would not "naturally occur" to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office Action, the requirement for written description has not been met.

Conclusions

7. Claims 20-22, and 25-31 are rejected. Claims 23 and 24 are objected for depending on rejected claims.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is set to expire within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

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any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

